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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,872	05/26/2000	Jeffrey Steven Albrecht	00JSA001	9690

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EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/579,872

Applicant(s)

ALBRECHT, JEFFREY STEVEN

Examiner

Luke Gilligan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. In the amendment filed 7/8/05, the following has occurred: claims 41-43 have been amended. Now, claims 21-43 are presented for examination.
2. The rejections under 35 U.S.C. 112 are withdrawn by the Examiner based on changes made by Applicant to the claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. Claims 21-25, 27-28, 31-32, and 35-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, U.S. Patent No. 6,161,095 in view of Kehr, U.S. Patent No. 5,642,731.
5. As per claim 21, Brown teaches a medical management system comprising: a personal communication device programmed to allow a patient to generate a record indicating a patient initiated decision to self administer a medical treatment (see column 5, lines 3-34); a database (see column 6, lines 48-57); a network coupling the personal communication device and the database to allow information to pass between the personal communication device and the database (see column 3, line 63 – column 4, line 6); wherein, the record generated includes a time the medical treatment was administered and additional information about the medical treatment administered (see column 5, lines 24-40); wherein, the personal communication device sends the record to the database over the network (see column 3, line 63 - column 4,

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line 6 and column 5, lines 48-57); and wherein the record is added to the database (see column 5, lines 48-57).

6. Brown does not explicitly teach generating, by a patient, a record of the patient's unforeseen self administration of a medical treatment. Kehr teaches a personal communication device that is programmed for generating, by a patient, a record of the patient's unforeseen self administration of a medical treatment (see column 15, lines 10-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Brown. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of providing enhanced patient care by providing greater communication between provider and patient especially with respect to unscheduled treatments as suggested by Kehr (see column 4, lines 14-20 of Kehr).

7. As per claim 22, Brown in view of Kehr teach the method of claim 21 as described above. Brown further teaches a part of the record is interactively generated by input from the patient and a part of the record is automatically generated by the personal communication device (see column 5, lines 24-40).

8. As per claim 23, Brown in view of Kehr teach the method of claim 21 as described above. Brown further teaches wherein the database is processed to initiate an automatic medication reorder (see column 3, lines 3-6 and column 4, line 43 – column 5, line 14).

9. As per claims 24 and 25, Brown in view of Kehr teaches the method of claim 21 as described above. Brown further teaches one or more communications devices coupled to the network and programmed to allow healthcare providers and pharmacists to access the database and to communicate with patients (see column 3, line 63 – column 4, line 34 and column 7, line 63 – column 8, line 19).

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10. As per claim 27, Brown in view of Kehr teach the method of claim 21 as described above. Brown does not explicitly teach receiving warning messages through the personal communication device indicating that the patient possesses tainted medication. Kehr teaches receiving warning messages through a personal communication device indicating that the patient possesses tainted medication (see column 22, lines 42-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Brown for the reasons given above with respect to claim 21.

11. As per claim 28, Brown in view of Kehr teach the method of claim 21 as described above. Brown further teaches wherein the database contains patient education material accessible to the patient (see column 4, lines 46-48 and column 4, line 57 – column 5, line 23; the examiner interprets “treatment regimen” information as a form of “education material”).

12. As per claim 31, Brown in view of Kehr teach the method of claim 21 as described above. Brown further teaches wherein the database is used to perform tracking and trending of medication administered by the patient (Brown; col. 2, line 66-col. 3, line 3 and col. 6, lines 8-14).

13. As per claim 32, Brown teaches a personal interactive medication logging apparatus comprising: a processor (see column 4, lines 35-42); a memory (see column 4, lines 35-42); a communications interface (see column 4, lines 52-57); a user interface to receive input from a patient and present information to the patient (see column 4, lines 35-42); software stored in the memory and executable on the processor for performing functions comprising: generating a record in response to patient input received from the user interface, wherein the record indicates a patient initiated decision to self administer a medical treatment (see column 5, lines 24-40); and the time the medical treatment was administered (see column 5, lines 24-40); and using the communications interface to transmit the record to a central database,

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outside the personal interactive medication logging apparatus (see column 5, lines 48-57); and using the communications interface to receive messages from medical professionals (see column 3, line 63 – column 4, line 51).

14. Brown does not explicitly teach generating, by a patient, a record of the patient's unforeseen self administration of a medical treatment and symptoms that preceded the treatment. Kehr teaches a personal communication device that is programmed for generating, by a patient, a record of the patient's unforeseen self administration of a medical treatment (see column 15, lines 10-24) and symptoms that preceded the treatment (see column 4, lines 14-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Brown. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of providing enhanced patient care by providing greater communication between provider and patient especially with respect to unscheduled treatments as suggested by Kehr (see column 4, lines 14-20 of Kehr).

15. As per claim 35, Brown in view of Kehr teach the database of claim 32 as described above. Brown further teaches the software is further capable of retrieving patient education material from the database via the communications interface (see column 4, lines 46-48 and column 4, line 57 – column 5, line 23).

16. Claims 36-38 recites substantially similar limitations to those already addressed in claim 21, 27 and 31 and, as such, is rejected for similar reasons as given above.

17. As per claim 39, Brown in view of Kehr teach the database of claim 36 as described above. Brown does not explicitly teach an experience that triggered symptoms and a response to treatment. Kehr teaches an experience that triggered symptoms and a response to treatment (see column 3, line 48 – column 4, line 4). It would have been obvious to one of ordinary skill in

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the art at the time of the invention to incorporate this feature into the system of Brown for the reasons given above with respect to claim 21.

18. Claim 40 recites substantially similar limitations to those already addressed in claim 21 and, as such, is rejected for similar reasons as given above.

19. As per claim 41-43, Brown in view of Kehr further teach all of the limitations of claim 40 as described above, and further teach the limitations of claims 41-43 for the same reasons.

20. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, U.S. Patent No. 6,161,095 in view of Kehr, U.S. Patent No. 5,642,731 and further in view of Cummings, Jr. (5,301,105).

21. As per claim 26, Brown in view of Kehr teach the method of claim 21 as described above. Brown does not explicitly teach one or more communications devices coupled to the network and programmed to allow insurance providers to access the database and to communicate with patients. However, this feature is old and well known in the art, as evidenced by Cummings' teachings with regards to one or more communications devices coupled to the network and programmed to allow insurance providers to access the database and to communicate with patients (see abstract and figure 1). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Brown with Cummings' teaching with regards to these limitations, with the motivation of providing patients with predetermined financial support (see abstract of Cummings).

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22. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, U.S. Patent No. 6,161,095 in view of Kehr, U.S. Patent No. 5,642,731 and further in view of Halvorson, U.S. Patent No. 4,847,764.

23. As per claim 29, Brown in view of Kehr teach the method of claim 21 as described above. Brown does not explicitly teach the wherein the database contains a product catalog. However, this feature is old and well known in the art, as evidenced by Halvorson's teachings with regards to a database that includes a product catalog (see column 36, lines 60-66). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Brown with Halvorson's teaching with regards to this limitation, with the motivation of enhancing the inventory control of medications within the system of Brown (see column 2, lines 39-53 of Halvorson).

24. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, U.S. Patent No. 6,161,095 in view of Kehr, U.S. Patent No. 5,642,731 and further in view of Campbell (Campbell, Sandy, "Accordant meets the challenges that rare chronic diseases pose for managed care," Health Care Strategic Management, August 1996).

25. As per claim 30, Brown teaches that the patient treatment regimen and protocol are stored in a database (Brown; col. 4, lines 43-48), but fails to expressly teach the database is tailored to the disease hemophilia. However, this feature is old and well known in the art, as evidenced by Campbell's teachings with regards to a database consisting of protocols and algorithms for treatments for diseases including hemophilia (Campbell; abstract). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Brown with Campbell's teaching with regards to this limitation, with the motivation of providing treatment regimens and

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protocols for patients suffering from hemophilia, thereby meeting disease management objectives (Campbell; abstract).

26. Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, U.S. Patent No. 6,161,095 in view of Kehr, U.S. Patent No. 5,642,731 and further in view of Glynn, U.S. Patent No. 5,774,865.

27. As per claim 33, Brown in view of Kehr teaches the method of claim 32 as describe above. Brown does not explicitly teach a bar code reader and wherein the software is further capable of accepting input from the patient via the user interface to activate the barcode reader and use the information retrieved from the barcode reader to add information to the record comprising the identity of a medication being taken by the patient as part of the medical treatment. However, this feature is old and well known in the art, as evidenced by Glynn's teachings with regards to a bar code reader and wherein the software is further capable of accepting input from the patient via the user interface to activate the barcode reader and use the information retrieved from the barcode reader to add information to the record comprising the identity of a medication being taken by the patient as part of the medical treatment (see abstract and column 4, lines 32-56). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to incorporate this feature into the system of Brown. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of enhancing the accuracy of the record keeping in Brown.

28. As per claim 34, Brown in view of Kehr teaches the method of claim 32 as describe above. Brown does not explicitly teach wherein the software is further capable of automatically generating part of the record, and presenting the record to the patient for review prior to the

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record's transmission to the database. However, this feature is old and well known in the art, as evidenced by Glynn's teachings with regards to wherein the software is further capable of automatically generating part of the record, and presenting the record to the patient for review prior to the record's transmission to the database (see; abstract and column 4, lines 32-56). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to incorporate this feature into the system of Brown. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of enhancing the accuracy of the record keeping in Brown.

Response to Arguments

29. In the remarks filed 7/8/05, Applicant argues in substance that (1) in Brown, patients cannot take medication at unscheduled times because it would violate any treatment regimen determined by a service provider; (2) Brown teaches away from the proposed combination because it cannot provide reminder messages for unscheduled acts; (2) there is no motivation to combine the teachings of Brown and Kehr.

30 In response to Applicant's argument (1), the Examiner respectfully submits that although a patient taking an unscheduled medication may violate a treatment regimen, there is absolutely nothing in the system of Brown that prevents a patient from taking unscheduled medication. Rather, Brown teaches a system that facilitates communication between patients and providers to optimize the patients' treatment and analyze patient compliance (see column 2, lines 31-37 of Brown). It appears that Applicant is suggesting that all patients using the system of Brown would never take unscheduled medications. However, if this were the case, there would be no reason to analyze compliance because all patients would only take their scheduled medication at their scheduled times. It is respectfully submitted that this is an unrealistic view of the real-

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world applicability of Brown and fails to take into consideration the level of knowledge available to one of ordinary skill in the art at the time of the invention.

31. In response to Applicant's argument 2, as described above, the Examiner respectfully submits that reminder messages do not prevent a patient from taking unscheduled medication. Rather, the provision of reminder messages is only to help remember when to take their scheduled medication and has nothing to do with what the patient may do on their own. Therefore, this argument is not found to be persuasive.

32. In response to Applicant's argument (3), the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). It is also noted that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, it is respectfully submitted that the cited portion of Kehr indicates that it would be helpful to know why a patient took a pill at an unscheduled time. When this is considered along with the fact that Brown is directed both monitoring and analyzing compliance along with the ability to alter treatments based on feedback from patients (see column 2, lines 37-42 of Brown), it is submitted that one of ordinary skill in the art would have been motivated to combine the teachings as described above in the rejections.

Conclusion

33. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

34. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (571) 272-6770. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

36. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

37. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CLG

10/02/05



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